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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,964	02/12/2002	Catherine M. Bitler	0258-US-CON1	7959

21835 7590 09/15/2005  
ELAN PHARMACEUTICALS, INC.  
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EXAMINER

WANG, CHANG YU

ART UNIT PAPER NUMBER

1649

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/074,964	<b>Applicant(s)</b> BITLER ET AL.	
	<b>Examiner</b> Chang-Yu Wang	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on February 12, 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-16, and claims 20-23 and 25 to the extent of cells exposed to no growth factor, drawn to a method of screening test compounds as candidates for treating or preventing ischemia-related cellular damage, classified in for example class 535, subclass 2.
- II. Claims 17-19 and 24 the extent of cells exposed to no growth factor, drawn to a method of treating ischemia-related neuronal damage, classified in for example class 514, subclass 2.
- III. Claims 20-23, and 25, drawn to a method of screening compounds as candidates for treating glaucoma comprising cells exposed to a growth factor, classified for example in class 535, subclass 2.
- IV. Claim 24 drawn to a method of treating glaucoma comprising cells exposed to a growth factor, classified in for example class 514, subclass 2.
- V. Claim 26 drawn to a method of treating a neurodegenerative disease, classified in for example class 514, subclass 2

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and III are related as combination and subcombination, and so as Invention II and IV. Inventions in this relationship are distinct if it can be

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shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination, a growth factor, as claimed because the effects and outcomes of neuronal cells exposed to a growth factor without an oxygen/glucose deprivation challenge are very different from those of with an oxygen/glucose deprivation challenge. The subcombination has separate utility such as enhancing neural survival, protection or differentiation. Therefore, these inventions are distinct because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Inventions I, III, and II, IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, first, the materials and methods, the equipments as well as the steps for screening test compounds (in Groups I and III) and for treating patients (in Groups II, IV and V) are very different. The equipments and methods for screening test compounds can be used for screening another materials. Second, the characteristics of each group of patients are very distinct in physiological conditions. The health status and symptoms are very different in the patients suffering from ischemia-related neuronal damage or glaucoma when compared to those with neurodegenerative

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diseases. In addition, the etiology and pathology are also very distinct in patients who suffer from ischemia-related neuronal damage in Groups II and IV when compared to those who suffer from neurodegenerative diseases in the Group V. The above reason also applies to the Groups IV and V. Third, since the pathological conditions are quite distinct among these different groups of patients, the responses to the treatment are also inherently very distinguishable. The medications among these distinct groups of patients are also different. Thus, the inventions I, II, III, IV and V are patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-V to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

***Species Election***

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

i. Species of primary excitable cell type selected from:

A) Retinal ganglion cells or B) Cardiac myocytes.

ii. Species of cell death selected from:

A) Apoptosis-related cell death, B) Necrotic cell death, or C) Non-apoptotic, non-necrotic cell death.

iii. Species of test compounds selected from:

A) A calcium channel blocker, B) An NMDA receptor antagonist, or C) A bis-benzimidazole

iv. Species of ischemia-related cell damage selected from:

A) Retinal neuronal damage associated with glaucoma,  
B) Neuronal cell damage in the central nervous system associated with cerebral ischemia, or  
C) Myocardial damage associated with myocardial infarction.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

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8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single designated group from Groups I-V and a species for

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each of designated groups i-iv for primary excitable cell type, type of cell death, type of test compounds and type of ischemia-related cellular damage to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species. It is noted that while one of groups i-iv may not be applicable to one of Groups I-V, Applicant must elect one of each in order to be fully compliant.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

14. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November




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15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
9-12-05

CYW  
September 1, 2005